



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,090	04/11/2007	Duncan C. Ferguson	235.00540101	5257

26813 7590 09/15/2008  
MUETING, RAASCH & GEBHARDT, P.A.  
P.O. BOX 581336  
MINNEAPOLIS, MN 55458-1336

EXAMINER
----------

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
----------	--------------

1646

MAIL DATE	DELIVERY MODE
-----------	---------------

09/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,090	<b>Applicant(s)</b> FERGUSON, DUNCAN C.	
	<b>Examiner</b> ZACHARY C. HOWARD	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, 19 and 22-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14, 17, 19 and 22-49 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)                      |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application            |
| Paper No(s)/Mail Date _____  | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment #1</u> . |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The preliminary amendment of 5/12/06 has been entered in full. Claims 15, 16, 18, 20, 21 and 50-54 are canceled. Claims 22, 25, 34, 37, 39, 41 and 43 are amended. Claims 1-14, 17, 19 and 22-49 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13, 37 and 38, drawn to a feline thyrotropin  $\beta$ -subunit polypeptide, a feline thyrotropin  $\alpha$ -subunit polypeptide, a yoked feline thyrotropin polypeptide, and pharmaceutical compositions thereof.

Group II, claims 14, 17, 19, 22-24 and 39-43, drawn to a polynucleotide encoding a feline thyrotropin  $\beta$ -subunit polypeptide, a vector comprising said polynucleotide, a polynucleotide encoding a feline thyrotropin  $\alpha$ -subunit polypeptide, a vector comprising said polynucleotide, a polynucleotide encoding a yoked feline thyrotropin polypeptide, a vector comprising said polynucleotide, and host cells comprising said vectors.

Group III, claims 25-28, drawn to an antibody that specifically binds to a feline thyrotropin  $\beta$ -subunit polypeptide, a feline thyrotropin  $\alpha$ -subunit polypeptide, or a yoked feline thyrotropin polypeptide.

Group IV, claims 29-33, drawn to a method of detecting physiological levels of feline thyrotropin in a sample.

Group V, claims 34-36, drawn to a method of treating a mammal comprising administering a feline thyrotropin heterodimer.

Group VII, claims 44-49, drawn to a method of making a feline thyrotropin polypeptide.

Art Unit: 1646

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475 (B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. However, in the instant case the prior art teaches a product that is encompassed by the first product recited in the claims (Group I above). The technical feature linking groups I-VII appears to be that they all relate to polypeptides related by sequence identity to the feline  $\alpha$ - or  $\beta$ -subunit.

Specifically, Group I encompasses an isolated feline thyrotropin  $\alpha$ -subunit polypeptide comprising at least 80% identity to SEQ ID NO: 4. Thus, claim 1 encompasses variants of SEQ ID NO: 1 with or more amino acid changes to SEQ ID NO: 1, including mutated variants. The recitation of "feline" as a descriptor of the polypeptide is not limiting because there is nothing to distinguish a mutated variant of SEQ ID NO: 1 from a variant of SEQ ID NO: 1 from another species. For example, the prior art teaches a porcine sequence with 96.8% similarity to the feline sequence of SEQ ID NO: 4 (see the record for Accession P0129 in the NCBI GenBank Protein Database, created 1986, 3 pages as printed). An alignment of the two sequences is attached to this Office Action as Sequence Alignment #1, which shows a difference of four amino acids between the two sequences. This naturally-occurring sequence is identical to a mutated variant of SEQ ID NO: 1 that is encompassed by the instant claims. As such, the technical feature linking the inventions of group I-VII does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

### ***Election of species***

In addition to the above restriction requirement, a further election of species is required as follows:

This application contains claims directed to more than one species of polypeptide. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (1) isolated thyrotropin  $\beta$ -subunit;
- (2) isolated thyrotropin  $\alpha$ -subunit;
- (3) yoked polypeptide of thyrotropin  $\beta$ -subunit and thyrotropin  $\alpha$ -subunit;

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

1. Claims 1-4, 14, 22-33, 39, 40 and 44-47 encompass species 1.
2. Claims 5-8, 17, 22-33, 39-42 and 44-49 encompass species 2.
3. Claims 9-13, 19, 22-40, and 43-46 encompass species 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The  $\alpha$  and  $\beta$ -subunits of thyrotropin are distinct polypeptides with different sequences. Each is capable of independent use from the other protein. Furthermore, while they can be used together in the yoked polypeptide species, prior art was cited above teaching an  $\alpha$ -subunit encompassed by the claims. Therefore, any technical feature linking the three

Art Unit: 1646

polypeptides does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./

Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646